

### **REMARKS**

Claims 1, 27, 29-33, 40-49, and 59-60 are pending and at issue in the present application. Applicants hereby affirm the election of Invention I in response to the restriction requirement, and therefore claims 29-33 are withdrawn from consideration on the merits. In view of the amendments and remarks presented herein, reconsideration and allowance of all remaining claims are respectfully requested.

The Office action rejects claims 1 and 40 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. More specifically, the Office action asserts that the phrase “the inner lumen pressure is greater than the outer lumen pressure” appearing in claims 1 and 40 is improper for positively reciting “a natural physiological condition.” Claims 1 and 40 are amended herein to no longer positively recite this subject matter, and therefore this ground of rejection must be withdrawn.

The Office action further rejects claim 28 under 35 U.S.C. § 112, second paragraph, for failing to provide sufficient antecedent basis for “the aperture” in the body. In response to this rejection, claim 28 is canceled and new claims 59 and 60 have been added. New claim 59 is similar to original claim 20 and recites an extension member having an aperture. New claim 60 is similar to original claim 28, and recites a suture looped through the aperture, proper antecedent basis for the suture being provided in claim 59. In view of the foregoing, this ground of rejection must now be withdrawn.

Additionally, the Office action rejects claims 1, 40-42, and 44-45 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,700,277 (“Nash”). Applicants traverse this ground of rejection.

Independent claim 1 as amended, as well as claims 27, 59, and 60 depending directly or indirectly therefrom, specifies an apparatus to intervascularly promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner lumen pressure is greater than the outer lumen pressure. The apparatus includes a flexible plug having a center, a top surface, and a bottom surface, the plug being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site. A release mechanism includes a

hemostatic material coupled to the center of the flexible plug and a resilient extension member coupled to the hemostatic material opposite the flexible plug, the release mechanism positioning and releasing to position and release the flexible plug intervascularely at the blood vessel puncture site.

Independent claim 40, as well as claims 41-49 depending directly or indirectly therefrom; specifies an apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner lumen pressure is greater than the outer lumen pressure. The apparatus includes a flexible disk to intervascularely seal a blood vessel puncture site, the disk being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site. A hemostatic body is provided to intravascularely seal the blood vessel puncture site, while a connector couples the flexible disk to the hemostatic body, the connector being positioned within a wall of the blood vessel puncture site.

The amendments to claims 1 and 40 are supported by the specification as originally filed at page 9, lines 1-3; page 12, lines 8-17; page 21, lines 9-13, page 23, lines 3-16; and Figs. 4D and 5. Accordingly, the amended claims contain no new matter.

The cited prior art fails to disclose or suggest a plug (claim 1) or a disk (claim 40) that is sized to circumferentially cover the blood vessel puncture site and that is sufficiently flexible to conform to and seal with the blood vessel puncture site, as specified in the currently pending claims. Instead, Nash discloses a closure device 20 having a sealing member 30, an intra-arterial anchor member 32, a positioning filament 34, and a locking member 36. The anchor member 32, identified by the Examiner as responsive to the claimed plug/disk, is described at Column 5, lines 50-60 of Nash as basically comprising:

...a thin, narrow, strip or bar of material...The strip is sufficiently rigid such that once it is in position within the artery or other vessel, duct, or lumen, it is resistant to deformation to preclude it from bending to pass back through the puncture through which it was first introduced.

As best shown in Fig. 1, the anchor member 32 is formed as an elongate strip having rounded ends. Because it is formed of a rigid material, it is sized so that, when oriented as shown in Figs. 1 and 2, it may be inserted through the puncture. Consequently, and again because it is a "rigid" member, the anchor member 32 cannot be sized to circumferentially cover the blood vessel

puncture site, as specified in the current claim, since that would prevent it from being capable of insertion through the puncture. Additionally, the rigidity of the anchor member 32 taught by Nash prevents it from being "sufficiently flexible to conform to and seal with the blood vessel puncture site as specified in the current claims.

Nash fails to disclose or suggest each element of claims 1 and 40, and therefore the anticipation rejection based thereon must be withdrawn. Furthermore, one of ordinary skill in the art would not be motivated to modify the anchor member of Nash to have the claimed sized and flexibility, as Nash specifically teaches against such modifications. Accordingly, the current claims are not rendered obvious in view of Nash.

Claims 27, 29-33, 41-49, and 59-60, which depend directly or indirectly from claims 1 and 40, are patentable over the cited prior art for the same reasons presented above.

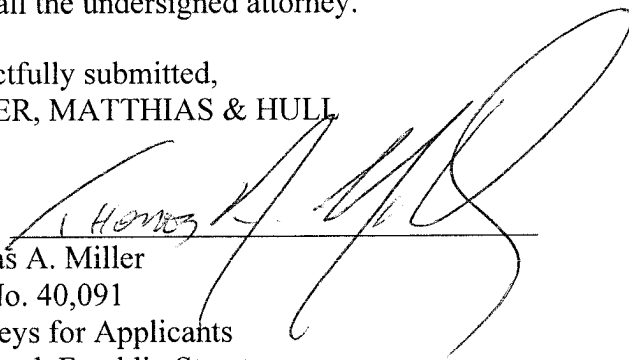
### **CONCLUSION**

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,  
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